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Proposed Maximum Residue Limit PMRL2013-96

Spinetoram

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on Bulb Vegetables and Tree Nuts to the product label of Delegate WG Insecticide, containing technical grade spinetoram, is acceptable. The specific uses approved in Canada are detailed on the label of Delegate WG Insecticide, *Pest Control Products Act* Registration Number 28776.

The evaluation of this spinetoram application indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for spinetoram is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to be added to the MRLs already established for spinetoram, are as follows.

Table 1 Proposed Maximum Residue Limits for Spinetoram

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Spinetoram	XDE-175-J: 1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12,13,14,16a,16b-hexadecahydro-14-methyl-(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)	0.1	Bulb Vegetables (Crop Group 3-07)
		0.02	Tree Nuts (Crop Group 14-11)

Common Name	Residue Definition	MRL (ppm)	Food Commodity
	and XDE-175-L: 1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-(2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*), including the metabolites N-demethyl-175-J: (2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-9-ethyl-14-methyl-13-{[(2*S*,5*S*,6*R*)-6-methyl-5-(methylamino)tetrahydro-2*H*-pyran-2-yl]oxy}-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-2-yl 6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranoside and N-formyl-175-J: (2*R*,3*S*,6*S*)-6-({(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-α-L-mannopyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-*d*]oxacyclododecin-13-yl}oxy)-2-methyltetrahydro-2*H*-pyran-3-yl(methyl)formamide		

ppm = parts per million

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for spinetoram in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Bulb Vegetables (Crop Group 3-07)	0.1	2 (Onion, green)	Not Established
Tree Nuts (Crop Group 14-11)	0.02	0.1 (Nut, tree, group 14)	0.01

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spinetoram up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data from field trials conducted in Canada on dry bulb onions were submitted to support the domestic use of Delegate WG Insecticide on bulb vegetables. In addition, green onion residue data from field trials conducted in Canada were reassessed within the framework of the current petition. Residue data from field trials conducted in the United States were reassessed within the framework of the current petition to support the domestic use of Delegate WG Insecticide on tree nuts.

Spinosad was applied to dry bulb onion and green onions at the proposed rate, and to almonds and pecans at exaggerated rates, and all crops were harvested according to label directions.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for spinetoram in/on bulb vegetables and tree nuts was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for bulb vegetables (Crop Group 3-07) and tree nuts (Crop Group 14-11).

Table A1 Summary of Field Trial Data Used to Support Maximum Residue Limits

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)	
			Min	Max
Dry bulb onions	Foliar broadcast ground/ 297–340	3–4	<0.02	<0.04
Green onions	Foliar broadcast ground/ 292–333	3–4	<0.04	<0.062
Almond nutmeats	Foliar/ 500.4–533.2	14	<0.02	<0.02
Pecan nutmeats	Foliar/ 536.8–545.9	13–14	<0.001	0.0076

PHI = preharvest interval; ppm = parts per million

Following the review of all available data, MRLs of 0.1 ppm and 0.02 ppm are recommended to cover residues of spinetoram in/on bulb vegetables and tree nuts, respectively. Residues of spinetoram in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors